IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9505

Bartle, J. August 7, 2018

Debra K. Browning ("Ms. Browning" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

---

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Rick E. Browning, Ms. Browning's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued . . .)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, the claimant's attorney must complete Part III if claimant is represented.

In November 2015, the claimant submitted a completed Green Form to the Trust signed by her attesting physician, Richard DiNardo, D.O., F.A.C.C. Based on an echocardiogram dated August 5, 2015,[4] Dr. DiNardo attested in Part II of

---

(continued . . .)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Because claimant's August 5, 2015 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated June 4, 2003 to establish her
(continued . . .)

Ms. Browning's Green Form that claimant suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $604,808.[5]

In February 2016, the Trust forwarded the claim for review by Zuyue Wang, M.D., one of its auditing cardiologists. In the audit, Dr. Wang concluded that there was no reasonable medical basis for finding that claimant had moderate mitral regurgitation because she determined that claimant's August 5, 2015 echocardiogram only demonstrated mild mitral regurgitation. In particular, she stated, "RJA/LAA = 2.8/15.4=18%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the regurgitant jet area ("RJA") in any apical view is

---

(continued . . .)
eligibility to receive Matrix Benefits. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. § IV.B.2.C.(2)(b). Given our disposition with respect to the level of claimant's mitral regurgitation, we need not address whether she established a reasonable medical basis for one or more of the five complicating factors.

equal to or greater than 20% of the left atrial area ("LAA"). See Settlement Agreement § I.22.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Browning's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, Ms. Browning argued that there was a reasonable medical basis for finding that her August 5, 2015 echocardiogram demonstrated moderate mitral regurgitation. In support, Ms. Browning submitted a statement from Dr. DiNardo in which he concluded in pertinent part that:

> Ms. Browning's echocardiogram showed that she was suffering from mitral regurgitation near the border between mild and moderate mitral valve regurgitation. Reasonable, competent doctors can and do differ when making an opinion about whether one has mild or moderate mitral valve regurgitation under such circumstances. I concluded to a reasonable medical certainty that the mitral valve regurgitation was moderate. Ms. Browning's other physical symptoms tended to support such a finding as she was suffering from chest pain and heart palpitations. Moreover, Ms. Browning's medical history showed that the condition of

---

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Browning's claim.

> her heart valves and her symptoms had been worsening over a long period of time. I believe that my opinion that the mitral valve regurgitation was moderate is more supported by the totality of Ms. Browning's medical history than is Dr. Wang's opinion and certainly cannot be said to lack a reasonable medical basis, which I am informed is the evaluative standard used by AHP for this opinion.[7]

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Wang submitted a declaration in which she again concluded that there was no reasonable medical basis for finding that Ms. Browning had moderate mitral regurgitation. Specifically, Dr. Wang stated:

> 10. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had moderate mitral regurgitation. Upon review in contest, I again reviewed the entire August 5, 2015 [echocardiogram of attestation], identified a regurgitant jet representative of the mitral regurgitation seen in real time. The mitral valve regurgitation is clearly mild with an RJA/LAA ratio of 18% (2.8/5.4). *See*, frame No. 23, a copy of which is annexed hereto as Exhibit B. I disagree with Dr. Dinardo's

---

7. Along with her contest materials, Ms. Browning also submitted an amended Green Form that set forth a claim for benefits related to her aortic valve. The Trust limited its review of Ms. Browning's claim to the properly submitted November, 2015 Green Form, and we decline to review the amended Green Form in the first instance. In any event, Ms. Browning abandoned that claim in her response to the Trust's Statement of the Case.

> [sic] contention that the patient's presentations of chest pain and heart palpitations support a reasonable medical basis for finding moderate mitral regurgitation. Such representations are not indicative of moderate mitral regurgitation. Some patients with moderate mitral regurgitation may even be asymptomatic. Chest pain and heart palpitations may result from a variety of medical conditions. The severity of mitral regurgitation seen in real time and the RJA/LAA ratio which I measured to be 18% was not borderline moderate. It is clearly less than the 20% threshold to find moderate mitral regurgitation.

The Trust then issued a final post-audit determination confirming that Ms. Browning was not entitled to Matrix Benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Browning's claim should be paid. On May 10, 2017, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9488 (May 10, 2017).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 15, 2017 and

the Claimant submitted a sur-reply on December 28, 2017. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for this finding, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for this finding, we must enter an

---

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge - helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

Ms. Browning argues in support of her claim that at least one other physician, Zane Darnell, M.D., determined that her October 2006 echocardiogram demonstrated moderate mitral regurgitation. Ms. Browning repeated her argument from contest that the presence of chest pain, shortness of breath, irregular heartbeats, and palpitations "are consistent with and tend to support a diagnosis of moderate mitral regurgitation." She also argues that Dr. DiNardo's determinations should be given more weight because they were made in the course of treatment rather than in the course of her claim. Ms. Browning contends that Dr. Wang is a "hired gun" of the Trust. Finally, Ms. Browning submitted an affidavit from Dalton McLean, M.D., who she hired to evaluate the August 5, 2015 echocardiogram. In his affidavit, Dr. McLean stated that:

> 7. I looked through the August 5, 2015 echocardiogram frames and selected frame 36 to show on the computer screen. Using the software, I outlined the two areas to be measured - the RJA and the LAA - and then clicked on a link causing the computer to generate the data for the two areas resulting in RJA/LAA of 3.48/16.94 for a ratio of 20.6%. I was not able to print out the frame at that time so I did so several days later with the assistance of one of the hospitals IT personnel. A copy of frame 36 is attached to this affidavit as Exhibit A showing the boundaries of the RJA and LAA that I measured. It also shows the

LAA but we could not print out a screen shot showing the RJA calculation. However, we were able to load the screen shot of frame 36 onto a compact disk so that it would show both the RJA and LAA measurements though the screen shot on the disk would not show the boundaries of the RJA and the LAA. If you look at both the printed screen shot and the screen shot on the disk of frame 36, you can see exactly what I measured and exactly what the software calculated as the RJA/LAA of 3.48/16.94 or a ratio of 20.54%. I believe that the RJA and LAA shown on frame 36 and their measurements are representative of what I saw in real time on the echocardiogram. I did not "cherry-pick" that frame as I reviewed the entire echocardiogram and also used the same methods to measure the RJA and LAA on the frame that Dr. Wang relied upon - frame 23. The results of my examination of the RJA and LAA on frame 23 were roughly the same as those for frame 36 as I will explain below.

8. [Ms. Browning's attorney,] Mr. [Gary L.] Beaver asked me to also look at frame 23 which was the frame that Dr. Wang had asserted showed a RJA/LAA ratio of 2.8/15.4 or 18%. I placed frame 23 on the computer screen to see if I obtained the same results that Dr. Wang did for that depiction. I outlined the two areas to be measured using the software and the initial result showed RJA/LAA areas of 4.35/16.47 for a ratio of 26%. I noted that part of the RJA that I measured was red in color on the screen so that there may be some argument that the red area ought not be included in the RJA. I used the software to measure the RJA a second time, this time excluding the red area, and the result showed RJA/LAA 3.35/16.47 for a ratio of 20.34%. I have provided as Exhibit B a copy of frame 23 that shows the outlines of the RJA and LAA that I measured. The oval area that I marked on the left side of the RJA is the part that I excluded in making the

> second calculation of the RJA. Again, I could not print out the screen shot while Mr. Beaver met with me on August 31, but did so on September 7, 2017, with assistance from hospital IT personnel. When we printed it, the print did not show the number calculations so we also put frame 23 on the compact disk which does show the RJA measurements of 4.35 and 3.35 and the LAA measurement of 16.47. Both measurements result in a RJA/LAA ratio greater than 20%.
>
> 9. Based on my review of the August 5, 2015 echocardiogram, I conclude to an absolute certainty that the August 5, 2015 echocardiogram shows that Ms. Browning had a RJA/LAA ratio of at least 20% and, therefore, I further conclude to a reasonable medical certainty that Ms. Browning had moderate mitral valve regurgitation under the definition used for the AHP Settlement.

In response, the Trust argues that Ms. Browning's challenges to Dr. Wang's credibility are unsupported. The Trust also contends that the applicable burden of proof here is whether a reasonable medical basis exists for the Green Form representation at issue, not who can collect more expert opinions. The Trust notes that while Dr. DiNardo said that reasonable, competent doctors can differ in their opinions, he did not identify any error in Dr. Wang's measurement of mitral regurgitation on the August 5, 2015 echocardiogram. Finally, the Trust argues that Dr. McLean's mere disagreement with Dr. Wang is not sufficient to carry the claimant's burden.

The Technical Advisor, Dr. Vigilante, reviewed the claimant's echocardiograms and concluded that there was no reasonable medical basis for finding that Ms. Browning had moderate mitral regurgitation. Specifically, Dr. Vigilante stated, in pertinent part:

> I reviewed the Claimant's echocardiogram of Attestation. This was a transthoracic echocardiogram with 45 images. The date was August 5, 2015. This was an excellent quality study with the usual echocardiographic views obtained. The Nyquist limit was appropriately set at 69 cm per second in the apical views. The left atrium was clearly enlarged on visual evaluation. Using electronic calipers, I determined that the left atrial antero-posterior diameter was 4.3 cm. This measurement was taken between the posterior root of the aorta and posterior left atrial wall at the level of the aortic valve. This line was perpendicular to the supero-inferior axis of the left atrium. I determined that the left atrium measured 5.9 cm in the supero-inferior dimension. This measurement was taken from the mitral annulus to the posterior left atrial wall and was perpendicular to the mitral annulus. I excluded pulmonary vein structures in this measurement.
>
> . . . Visually, only mild mitral regurgitation was noted in the apical four and apical two chamber views. I was able to easily measure the RJA and LAA using the electronic tracing method in both the apical four and two chamber views. In the apical four chamber view, the largest representative RJA was 3.52 cm2 in loop 23. The LAA in the apical four chamber view was 22.55 cm2. This was most accurately measured in loop 20. Therefore, the accurate RJA/LAA ratio in the apical four

chamber view was 15.6% qualifying for mild mitral regurgitation in the apical four chamber view. The LAA measurements of 15.4 cm2 measured by Dr. Wang and 16.47 cm2 measured by Dr. McLean are inaccurately small and are not consistent with left atrial enlargement. The correct left atrial area was 22.5 cm2 in the apical four chamber view which is consistent with left atrial enlargement. In the apical two chamber view noted in loop 36, I determined that the RJA was 3.72 cm2 and the LAA was 24.43 cm2. Therefore, the RJA/LAA ratio in the apical two chamber view was 15.2% diagnostic of mild mitral regurgitation. Dr. McLean's LAA measurement of 16.94 cm2 in the apical four chamber view is inaccurately small and again not consistent with left atrial enlargement. My measurements of the RJA/LAA ratios in the apical four chamber and apical two chamber views correlate with the visual estimation of mild mitral regurgitation seen in real time. There were no cardiac cycles that approached the threshold of moderate mitral regurgitation.

. . . .

I reviewed Dr. McLean's screen shots submitted on a CD. Once again, his measurements of the LAA were incorrectly small. His measurements of the RJA of 3.35 cm2 in the apical four chamber view and 3.48 cm2 in the apical two chamber view were similar to my RJA measurements.

. . . .

In response to Question 1, there is no reasonable medical basis for the finding of moderate mitral regurgitation on the evaluated studies. All of these studies clearly demonstrated mild mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on any of these

studies even taking into account inter-reader variability.

In her response to the Technical Advisor Report, Ms. Browning argues that each of the physicians who have reviewed her echocardiograms have provided different measurements of the level of her mitral regurgitation. In addition, Ms. Browning contends that the court should take into consideration that she has been harmed by Diet Drugs, that whether she has mild or moderate mitral regurgitation is a "close question," that she likely will need mitral surgery in the future, and that she had aortic valve surgery after the deadline to submit a claim for Matrix Benefits.

After reviewing the entire show cause record, we find that Ms. Browning's arguments are without merit. As an initial matter, the claimant's attempt to refute the specific conclusions of the auditing cardiologist and the Technical Advisor falls short. Although she submitted statements from a number of cardiologists, neither claimant nor her experts identified any specific errors in the conclusions of the auditing cardiologist.[9] In fact, they simply provided their own measurements of Ms. Browning's RJA/LAA, and her attesting physician even observed that the level of Ms. Browning's mitral

---

9. For this reason as well, we disagree with claimant that Dr. DiNardo's opinion is entitled to more weight because it was rendered in the context of treatment.

regurgitation is "near the border." Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying specific errors by them is insufficient to meet a claimant's burden of proof.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Browning had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable when the auditing cardiologist and the Technical Advisor concluded that claimant's RJA/LAA ratio was less than 20%, both visually and by measurement. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation would allow a claimant to recover Matrix Benefits with an RJA/LAA ratio that does not meet the definition under the Settlement Agreement and would render meaningless this critical provision of the Settlement Agreement.[10]

---

10. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on any

(continued . . .)

Finally, contrary to the suggestion of Ms. Browning, causation of her medical condition is not at issue in resolving her claim for Matrix benefits. Rather, claimant is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which the qualification occurred. . . .

Mem. in Supp. of PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> . . . [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. The Settlement Agreement clearly and unequivocally requires a claimant to establish, among other things, that he or she has at least moderate mitral regurgitation to recover Level II Matrix Benefits for damage to her mitral valve. We must apply the Settlement Agreement as written. Accordingly,

---

(continued . . .)
of these studies even taking into account inter-reader variability."

claimant's argument that her current medical condition is the result of her ingestion of Diet Drugs is irrelevant.

For the foregoing reasons, we conclude that Ms. Browning has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Browning's claim for Matrix A-1, Level II benefits.